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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/867,914

05/30/2001

Neil Andrew Williams

5440US.cip

8062

26850

7590

05/18/2004

MARY M. KRINSKY, Ph. D., J.D.  
PATENT ATTORNEY  
79 TRUMBULL STREET  
NEW HAVEN, CT 06511

EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/867,914	<b>Applicant(s)</b> WILLIAMS ET AL.	
	<b>Examiner</b> Michael Borin	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 50-68 is/are pending in the application.
- 4a) Of the above claim(s) 54, 58 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-53, 55-57 and 60-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Status of Claims***

1. Amendment and response filed 03/19/2004 is acknowledged. Claims 10-, 13-49 are canceled. Claims 50-68 are pending. Applicant elected EtxB as agent and insulin as antigen. Claims 54,58,59 are withdrawn from consideration as drawn to non-elected species. Claims 50-53,55-57,60-68 are examined to the extent they read on the elected species.

### ***Priority***

2. This application is continuation-in-part of application 09/999458. As the parent application did not address compositions comprising insulin, the claims of instant application drawn to such compositions do not have benefit of earlier filing date of prior application(s) and have priority date of this application, 05/30/2001.

### ***Claim Objections***

3. Use of abbreviation GM-1 (claims 50,51,65-68) is noted. For clarity "ganglioside GM-1" is suggested to be used at the first appearance of the abbreviated term.

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4. Claims 55,56 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

***Claim Rejections - 35 U.S.C. § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 50-53,55-57,60-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 50,65-68 use term "agent" twice. It is not clear whether there are two different agent, or antibody "agent" is one of the members of Markush group addressed as "an agent". Further, which "said agent" is addressed at the end of the claims? As applicant selected EtxB as agent, the claims are addressed as compositions of EtxB.

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B. It is not clear, whether the term "agent" used in the claims means a single compound or a composition.

**Claim Rejections - 35 U.S.C. § 102 and 103.**

6. Claims 50-53,55-57,60-68 are rejected under 35 U.S.C. 102(b) as anticipated by Uda et al. (US 554378).

The instant claims are drawn to pharmaceutical composition comprising EtxB. Further, dependent claims (claims 53,57) recite antigen, such as insulin, as an additional component.

Uda teaches composition comprising B subunit of Etx and insulin. See claims 1,7,14.

In regard to intended use recited in the claims, arguments related to the intended use of the composition are of little relevance in determining the patentability of the composition. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). Suggested use limitations do not impart patentability to composition claims where the composition is otherwise anticipated by the prior art.

7. Claims 50,51,52,55,56,60-63 are rejected under 35 U.S.C. 102(b) as anticipated by Ochi et al (CA 2084120; Database Caplus, DN 121:170550), or Amin

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et al (Protein Expression and Purification 5, 198-204, 1994), or Wooley et al.(Database Medline, DN 95283386; Annals of the Rheumatic Diseases, 04/1995,54 (4), 298-304)

The instant claims are drawn to pharmaceutical composition comprising EtxB.

The references teach compositions comprising EtxB. See abstracts.

In regard to intended use recited in the claims, arguments related to the intended use of the composition are of little relevance in determining the patentability of the composition. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). Suggested use limitations do not impart patentability to composition claims where the composition is otherwise anticipated by the prior art. As for the effective dose, the instant claims do not specify the dosage to be used; therefore, the references are assumed to teach the concentration as claimed.

***Conclusion.***

8. No claims are allowed
9. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 10, 2004

MICHAEL BORIN, PH.D.  
PRIMARY EXAMINER

